

Amendments to the Specification:

Please replace the paragraph beginning at page 1, line 1, with the following amended paragraph:

This application is a divisional of U.S. Patent Application Serial No. 09/753,786, filed January 2, 2001, now allowed, which is a continuation-in-part of ~~claims priority to U.S. Provisional Application No. 60/037,620 filed February 12, 1997, and U.S. Patent Application Serial No. 09/022,688~~ 09/022,688, filed February 12, 1998, now U.S. Patent No. 6,168,593, which claims priority from U.S. Provisional Application No. 60/037,620, filed February 12, 1997, the entire contents of each application being incorporated herein by this reference.

Please replace the paragraph beginning at page 4, line 11, with the following amended paragraph:

In a further embodiment of the invention an apparatus for electrosurgical treatment of a body is disclosed. The apparatus comprises an elongated probe member having proximal and distal extremities, a handle connected to the proximal extremity and an electrode carried by the distal extremity, the probe member including a shaft having proximal and distal ends and a distal opening, the electrode including a flat plate and a cap, the plate being fixed to the distal end of the shaft and at least partially covering the distal opening, the ~~[[a]]~~ cap enclosing the plate and a portion of the distal end of the shaft.

Please replace the paragraph beginning at page 4, line 26, with the following amended paragraph:

FIGS. 3A-B show the tool tip of ~~[[FIG.]]~~ FIGS. 2A-C in a surgical instrument.

Please replace the paragraph beginning at page 4, line 27, with the following amended paragraph:

~~FIGS.~~ FIGS. 4A-E show a surgical instrument with an integral off-axis tip.

Please replace the paragraph beginning at page 5, line 6, with the following amended paragraph:

The invention comprises improved electrodes used for electrosurgical operations, ~~[[any]]~~ an apparatus incorporating such electrodes, and a general method for making an off-axis electrode useful for arthroscopic surgery. The electrosurgical electrode, in its preferred embodiments, comprises a metal conductor having a first external surface area and having a convex body, a flat face on the body, and a connector for attaching the body to an electrosurgical probe handle. This preferred electrode shape will be used to describe preparation of an electrode of the invention, but those skilled in the arts of making and manipulating solid metal bodies will recognize that other shapes can be manufactured in a similar manner. The preferred electrode bodies can readily be formed from a spherical metal body blank by grinding one region with a flat grinding element to produce a flat face, before or after drilling (or otherwise providing) a location to attach the electrode to an elongated probe.

Please replace the paragraph beginning at page 7, line 8, has been amended as follows:

In all of these operations, current and voltage are used to calculate impedance. An operator-set level of power and ~~[[for]]~~ temperature may be determined, and this level can be maintained manually or automatically if desired. The amount of RF energy delivered controls the amount of power. Feedback can be the measurement of impedance or temperature and occurs either at the controller or at the RF source if it incorporates a controller. Impedance measurement can be achieved by supplying a small amount of nontherapeutic RF energy. Voltage and current are then measured to confirm electrical contact. Accordingly, it is well within the skill of the art to determine satisfactory optimum operating conditions for electrodes of the invention having different active electrode areas from those exemplified herein. Circuitry, software and feedback to a controller result in full process control and are used to change (i) power (modulate) – including RF, incoherent light, microwave, ultrasound and the like, (ii) the duty cycle (on-off and wattage), (iii) monopolar or bipolar energy delivery, (iv) fluid

(electrolytic ~~solution~~solution) delivery, flow rate and pressure and (v) determine when ablation is completed through time, temperature and/or impedance.

Please replace the paragraph beginning at page 7, line 23, with the following amended paragraph:

The present invention provides a general method of manufacturing off-axis electrosurgical electrodes, by preparing a metal conductor having a first external surface area and having a first body shape and a connector for attaching the body to an electrosurgical probe handle, applying an insulating layer to cover all of the first external surface of the metal conductor, and removing a portion of the insulating layer at a selected second area of body shape, the second area being positioned on the metal conductor so that a line from a geometric center of the second area and substantially perpendicular to the second area intersects the principal axis of the probe at an angle, the axis being defined by the probe handle and the metal conductor upon attachment of a probe handle to the connector, generally through an elongated linear neck. Since the body of the electrode is formed from metal that is harder than the insulators commonly used in such electrodes, a grinding process can be used to remove a selected portion of an initially applied layer that covers the entire external surface of the electrode body. Care may need to be taken with softer metals if their original shape is to be maintained, but selection of grinding conditions based on the hardness ~~[[harness]]~~ of the material being removed are well known in the grinding art. In an embodiment of the invention insulating material on a flat surface is readily removed using a grinding disk; if desired a flat face can be formed on the electrode at the same time by using a grinding material harder than both the insulator and the metal used in the disk. Such a technique is particularly useful with softer metals, such as gold. Insulating material on a convex surface can be removed by a wire brush or a specially shaped grinding wheel. In ~~[[an]]~~ another embodiment the probe surface can be masked in the tip region. Insulation material can then be applied to the probe. The mask is then removed exposing the conductive tip. Any electrode formed by the manufacturing process described here is also part of the present invention.

Please replace the paragraph beginning at page 9, line 4, with the following amended paragraph:

FIGS. 2A-C show an alternate embodiment of the detachable tip to that discussed above in connection with FIGS. 1A-C. In this embodiment the entire detachable tip 200 may be comprised of a conductive material. An annular cavity 102B is defined within both the tapered shaft 108B and the arcuate extension 104B of the detachable tip. At a terminus of the arcuate extension a flat surface 120B is defined. Portions of the arcuate extension are covered with insulator 260 so as to localize the RF generation to flat surface 120B. Within the annular cavity 102B of the generally conducting detachable tip 200, both the RF and thermal couple connections are made. Because the detachable tip is generally conducting, no through hole ~~[[hold]]~~ to the flat surface 120B is required. Instead, thermal couple 112A is bonded to an interior surface of the annular cavity and wires 112B to that thermal couple extend from the distal end of the tapered shaft 108B. The RF wire 110B ~~[[11 OB]]~~ terminates in a bond 110A ~~[[11 OA]]~~ to the interior surface of the annular cavity.

Please replace the paragraph beginning at page 9, line 30, with the following amended paragraph:

FIGS. 3A-B show the detachable tip assembled with a surgical instrument 350. FIG. 3A shows the surgical instrument to include a handle 354, an extended probe or shaft 352 and the detachable tip 200 at a distal end of the probe 352. The handle is attached to the proximal end of ~~[[end~of]]~~ the probe. FIG. 3B shows the detachable tip 200 frictionally affixed within the distal end of probe 352. Probe 352 is tubular in cross-section and has an interior annular surface dimensioned to press fit with the exterior surface of tapered shaft 108B. Thus, the detachable tip is fastened to the distal end of probe 352. In alternate embodiments the tip can be fastened to the shaft by press fit, by mechanical fastener, by an interlocking action, by an adhesive compound, a bonding compound, by braising or by welding, for example. Electrical connections to both the

RF and thermal couple connections discussed above in connection with FIGS. 2A-C extend the length of the probe to power and control connections within the handle 354.

Please replace the paragraph beginning at page 10, line 12, with the following amended paragraph:

FIGS. 4A-E show an alternate embodiment for the off-axis RF tip of the current invention. The tip in these embodiments is integrated with the probe 352. The probe has a distal end 400 on which various embodiments of arcuate extensions 404B-E are shown in, respectively, FIGS. 4B-E. These arcuate extensions can be formed on the distal end of the probe through fabrication steps such as swaying, rotoforming, bending, etc. The probe may be solid or tubular in cross-section. In embodiments where the probe is solid, it may be made of a conductive material coated with an insulator 460B-E. At the terminus of the probe the insulating covering ~~[[420B-E]]~~ 460B-E ceases and an exposed portion of the probe forms a conductive electrode on the tip. Planar electrode surfaces 420B-E are shown in, respectively, FIGS. ~~[[4BE]]~~ 4B-E. RF connection can be made to the probe within the handle. The electric current will be carried the length of the conductive probe and will radiate from the flat surfaces 420 at the exposed probe tip 406B-E also shown respectively in FIGS. 4B-E. In an alternate embodiment of the current invention the probe is annular in cross-section and may be made from an insulating or conductive material. In the event the probe is made from an insulating material, the probe tip 406B-E shown in, respectively, FIGS. 4B-E may be comprised of a conductive material such as silver solder or conductive metallic powder. RF and thermal couple connections may be made to this conductive material 406 through wires extending from the handle through the annular opening within the probe 352 to the conductive tip material 406. The flat surfaces 420B-E may be formed on the tip by grinding and allow radiation of RF energy from an electrode surface whose normal axis is off the longitudinal axis about which the probe 352 is defined.

Please replace the paragraph beginning at page 11, line 4, with the following amended paragraph:

[[FIGS:]] FIGS. 5A-B show cross-sectional views of the integrated off-axis tip discussed above in connection with FIGS. 4A-E. FIG. 5A shows an embodiment in which the probe 352A is fabricated from a conductive material. FIG. 5B shows an embodiment in which probe 352B may be fabricated from an insulating material. The conductive probe 562A shown in FIG. 5A is covered with an insulating material 560. This material covers all portions of the probe with the exception of the distal end. The probe has an arcuate extension 404E. The probe may have an annular cavity 564 in cross-section. In alternate embodiments the probe may be solid in cross-section. At the distal end of the probe, a conductive material 406E fills the annular opening and defines a flat electrode surface 420E. A normal to this surface is in the embodiment shown off-axis or in the embodiment shown orthogonal to the longitudinal axis of the probe 352A. RF power is supplied to the conductive material 406E via the conductive probe 562A from an RF attachment in the handle 354. An RF junction 510A to an RF delivery wire 510B is made to the proximal end of the probe where it joins to handle 354.

Please replace the paragraph beginning at page 11, line 19, with the following amended paragraph:

In FIG. 5B the probe 562B defines an annular cavity 564 extending from the proximal to the distal end of the probe. At the distal end of the probe an arcuate extension 404E is defined. At the terminus of the probe a conductive material 406E fills the annular opening and defines a flat electrode surface 420E. Because the probe is generally insulating, a connection is made between RF delivery wire 510B, which extends the length of the annular cavity of the probe and forms a junction 510A with the conductive material 406E. Either embodiment shown in [[FIG.]] FIGS. 5A or 5B can additionally include a thermal couple to provide temperature feedback to an RF power source.

Please replace the paragraph beginning at page 11, line 28, with the following amended paragraph:

~~Although,~~Although each of the above mentioned embodiments ~~[[disclose]]~~ discloses an electrode surface which is flat it will be obvious to those skilled in the art that other surface profiles including concave and convex may also be utilized for the off-axis electrodes. Choice of surface profile will depend on the surgical environment. For example, in joints a flat electrode surface allows a probe with a low form factor. Additionally, a flat surface allows a larger contact area between the electrode and the surgical site. A concave surface may have the further advantage of isolating the surgical site from surrounding saline solution. The isolation of the concave design allows better thermal conductivity and therefore reduced thermal fluctuation.

Please replace the paragraph beginning at page 12, line 11, with the following amended paragraph:

FIGS. 6 and 7A-B show an alternate embodiment to the probes shown in FIGS. 1-5. In these embodiments, the tip itself is formed from the distal end of the probe via machining operations such as swaying, thermal forming, bending, etc. No conductive material is required and no attachable/detachable tip is required. Instead, the terminus of the probe is formed into an off-axis tip. In the embodiment shown in FIG. 6, the probe 652 is made from a conductive material 662 about which an insulating shell 660 is formed. The insulating shell can be formed in a variety of fashions. In one embodiment the insulating shell can be formed by heat shrink tubing which is slipped over the conductive probe and to which heat is applied to cause it to conform to the exterior of the probe. In an alternate embodiment, the probe itself after being formed can be dipped in an insulating solution. In still another embodiment, the probe can be coated with a powdered insulator which is activated by temperature to conform to the exterior surface of the probe. (In one such embodiment, Corvel® nylon coating may be used and is available from Morton Powder Coatings, P.O. Box 15240, Reading, PA 19612-5240, (800) 367-3318). In FIG. 6 arcuate surfaces 604B-C are formed on opposing sides of the distal end of the probe. As shown in cross-sectional ~~[[view, A-A]]~~ view A-A, an arcuate extension 604A is also formed at the terminus of the probe, thereby positioning the tip of the probe 620 so as to form a surface the normal to which is off the longitudinal axis about which the probe itself is defined.

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The tip itself is further formed to pinch or close the opening of annular cavity 664. This has the advantage of forming a longitudinal electrode surface 620 which may, with appropriate shaping operations such as grinding, offer a cutting surface or scraping surface which can be utilized in conjunction with the cutting or cauterizing capability of RF alone.